REMARKS

Claims 1-49 are pending in this application. By this Amendment, claims 1, 27, and 47 are amended, and new claims 48 and 49 are added. Support for the amendments to the claims may be found, for example, in the specification at Figures 11 and 12. No new matter is added. Reconsideration of the application based on the above amendments and the following remarks is respectfully requested.

I. <u>Personal Interview</u>

The courtesies extended to Applicants' representatives by Examiner Bowers at the interview held August 4, 2009 are appreciated. The reasons presented at the interview as warranting favorable action are incorporated into the remarks below, which constitute Applicants' record of the interview.

II. Rejections Under 35 U.S.C. §103

A. Toledo-Pereyra, Bacchi, and Cannon

The Office Action rejects claims 1-3, 7-22, 26, and 47 under 35 U.S.C. §103(a) as having been obvious over the combination of U.S. Patent No. 4,186,565 to Toledo-Pereyra ("Toledo-Pereyra"), U.S. Patent No. 5,285,657 to Bacchi et al. ("Bacchi"), and U.S. Patent Application Publication No. 2008/0032398 to Cannon et al. ("Cannon"). Applicants respectfully traverse the rejection.

By this Amendment, independent claim 1 is amended to recite the tube frame "configured to hold a plurality of tubes at respective predetermined positions where they are directly connectible to a plurality of tubes in the portable housing through at least one of the one or more openings, each of the predetermined positions corresponding to a location of the one or more openings."

Toledo-Pereyra fails to disclose a tube frame holding tubes at predetermined positions, "each of the predetermined positions corresponding to a location" of an opening in

a portable housing. If anything, Toledo-Pereyra discloses that the tubes curve and lie freely between their inlet and outlet positions. (See Toledo-Pereyra's Figs. 1 and 2). Thus, Toledo-Pereyra does not teach a frame configured to hold tubes at predetermined positions that correspond to locations of openings in the portable housing.

The Office Action, on page 6, asserts that Cannon discloses using a fastener to secure the tubing to a frame assembly. The Office Action further asserts that it would have been obvious to combine Cannon and Toledo-Pereyra to modify the tube assembly of Toledo-Pereyra "to ensure that the flow paths [of the tubes] do not become tangled or crushed during operation." (See Office Action at page 6).

By this Amendment, claim 47 is amended to recite "a tube frame configured to hold a plurality of tubes..., wherein the tubes are held by the tube frame on substantially a same plane." The applied references do not disclose this claim feature.

Toledo-Pereyra discloses placing tubes in any configuration in a large box, and connecting their ends to various areas on the apparatus. Thus, Toledo-Pereyra fails to disclose or reasonably suggest a tube frame that holds tubes at predetermined positions "on substantially a same plane." Bacchi and Cannon fail to cure this deficiency of Toledo-Pereyra with respect to claim 47.

Claims 1 and 47 are directed to an apparatus that is specifically configured to allow a simple and convenient connection interface between a tube frame and a portable housing, rather than an apparatus that merely provides an organized tube system. Moreover, a *prima* facie case of obviousness cannot be established unless there existed some reason or rationale to sufficiently motivate a person having ordinary skill in the art to combine the references relied upon and achieve the *specific* claimed invention. (See MPEP §2143.01).

The obviousness rejection in the Office Action and as asserted during the personal interview is not supported with a clear and explicit articulation of reasons why the claimed

invention allegedly would have been obvious, including a reasonable rationale as to why the applied references would have been combined or modified to meet the claimed limitations.

(See MPEP §§2141 and 2142). In particular, during the personal interview, the Examiner argued that one of ordinary skill in the art would simply be motivated by a need for organization of the tubes in Toledo-Pereyra to achieve the above-mentioned claim limitations. However, rejections for obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

Neither Toledo-Pereyra nor Cannon discloses or would have reasonably suggested holding the tubes at predetermined positions, "each of the predetermined positions corresponding to a location of the one or more openings" in the portable housing. Modifying the apparatus of Toledo-Pereyra to 1) move the oxygenator, bubble trap, and pump unit inside the tube box, as the Office Action alleges that Bacchi discloses; 2) incorporate the fixed tubes of Cannon; and further 3) rearrange the tubes in the tube box to each correspond to an opening in the floor of the organ receptacle, is a substantial modification that would not have been obvious in the absence of improper hindsight reasoning. It is impermissible to assert a *prima facie* case of obviousness using "knowledge gleaned only from applicant[s'] disclosure;" rather a determination of obviousness must rely only on what the prior art teaches or reasonably suggests to one of ordinary skill in the art at the time of the invention. (See MPEP §2145(X.A.)).

Moreover, the substantial modification suggested of Toledo-Pereyra would improperly change the principle of operation of Toledo-Pereyra. (See MPEP §2143.01). In other words, the apparatus of Toledo-Pereyra was not intended to be modified to move the oxygenator, bubble trap, and pump unit inside the tube box, nor would Toledo-Pereyra operate as intended

if the organ cassette were modified to accept tubes through its floor. Therefore, the suggested modification of Toledo-Pereyra is improper.

Bacchi fails to cure the deficiencies of Toledo-Pereyra and Cannon with respect to the independent claims for the same reasons discussed above with regard to Toledo-Pereyra and Cannon.

Thus, the combination of Toledo-Pereyra, Bacchi, and Cannon would not have rendered obvious claims 1 and 47. Claims 2, 3, 7-22, and 26 variously depend from claim 1 and, thus, would also not have been rendered obvious by the combination of applied references for at least the same reasons. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

B. Toledo-Pereyra, Bacchi, Cannon, and Hassanein

The Office Action rejects claims 4 and 5 under 35 U.S.C. §103(a) as having been obvious over the combination of Toledo-Pereyra, Bacchi, Cannon, and U.S. Patent No. 6,046,046 to Hassanein ("Hassanein"). Applicants respectfully traverse the rejection.

The deficiencies of Toledo-Pereyra, Bacchi, and Cannon with respect to claim 1 are discussed above. Hassanein fails to cure the deficiencies of the applied references with respect to claim 1.

Thus, the combination of Toledo-Pereyra, Bacchi, Cannon, and Hassanein would not have rendered obvious claim 1. Claims 4 and 5 depend from claim 1, and, thus, would also not have been rendered obvious by the applied references for at least the same reasons.

Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

C. Toledo-Pereyra, Bacchi, Cannon, and Fahy

The Office Action rejects claims 6 and 23-25 under 35 U.S.C. §103(a) as having been obvious over the combination of Toledo-Pereyra, Bacchi, Cannon, and U.S. Patent No. 5,586,438 to Fahy ("Fahy"). Applicants respectfully traverse the rejection.

The deficiencies of Toledo-Pereyra, Bacchi, and Cannon with respect to claim 1 are discussed above. Fahy fails to cure the deficiencies of Toledo-Pereyra, Bacchi, and Cannon with respect to claim 1. Thus, the combination of Toledo-Pereyra, Bacchi, Cannon, and Fahy would not have rendered obvious claim 1. Claims 6 and 23-25 variously depend from claim 1 and, thus, would also not have been rendered obvious by the applied references for at least the same reasons. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

D. Bacchi and Cannon

The Office Action rejects claims 1-3, 7, 8, 11-15, 17-22, 26, and 47 under 35 U.S.C. §103(a) as having been obvious over the combination of Bacchi and Cannon. Applicants respectfully traverse the rejection.

By this Amendment, claim 1 is amended to recite the tube frame "configured to hold a plurality of tubes at respective predetermined positions where they are directly connectible to a plurality of tubes in the portable housing through at least one of the one or more openings, each of the predetermined positions corresponding to a location of the one or more openings."

Bacchi does not disclose and would not have rendered obvious a tube frame holding tubes at predetermined positions, "each of the predetermined positions corresponding to a location of the one or more openings" in a portable housing. Instead, Bacchi discloses a single free-flowing tube within a box. (See Bacchi's Fig. 2). Contrarily, claim 1 requires a plurality of tubes in fixed predetermined positions within a tube frame, "each of the predetermined positions corresponding to a location of the one or more openings" in a portable housing. As such, the claimed apparatus is easily and quickly assembled or disassembled. Cannon fails to cure the deficiencies of Bacchi with respect to claim 1 for the same reasons discussed above.

By this Amendment, claim 47 is amended to recite "a tube frame configured to hold a plurality of tubes..., wherein the tubes are held by the tube frame on substantially a same plane." The applied references do not disclose this claim feature.

Bacchi discloses a single tube, rather than a plurality of tubes. Therefore, Bacchi does not disclose or render obvious holding a plurality of tubes within a tube frame "on substantially a same plane." Cannon fails to cure the deficiencies of Bacchi with respect to claim 47.

Thus, the combination of Bacchi and Cannon would not have rendered obvious claims 1 and 47. Claims 2, 3, 7, 8, 11-15, 7-22, and 26 variously depend from claim 1 and, thus, would also not have been rendered obvious by the applied references for at least the same reasons. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

E. Bacchi, Cannon, and Hassanein

The Office Action rejects claims 4 and 5 under 35 U.S.C. §103(a) as having been obvious over the combination of Bacchi, Cannon, and Hassanein. Applicants respectfully traverse the rejection.

The deficiencies of Bacchi and Cannon with respect to claim 1 are discussed above. Hassanein fails to cure the deficiencies of Bacchi and Cannon. Thus, the combination of Bacchi, Cannon, and Hassanein would not have rendered obvious claim 1. Claims 4 and 5 depend from claim 1 and, thus, would also not have been rendered obvious by the applied references for at least the same reasons. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

F. Bacchi, Cannon, and Fahy

The Office Action rejects claims 6 and 23-25 under 35 U.S.C. §103(a) as having been obvious over the combination of Bacchi, Cannon, and Fahy. Applicants respectfully traverse the rejection.

The deficiencies of Bacchi and Cannon with respect to claim 1 are discussed above. Fahy fails to cure the deficiencies of Bacchi and Cannon. Thus, the combination of Bacchi, Cannon, and Fahy would not have rendered obvious claim 1. Claims 6 and 23-25 variously depend from claim 1, and, thus, also would not have been rendered obvious by the applied references for at least the same reasons. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

III. Claim 13

As discussed with and agreed upon by Examiner Bowers during the personal interview, none of the applied references disclose, nor would any combination of the applied references render obvious, a tube frame that is "connectible to a connection device of [a] portable housing." Toledo-Pereyra discloses that the organ cassette is "mounted" on the tube box, rather than connected to it. (*See* Toledo-Pereyra at column 1, lines 54-57). Bacchi discloses a bracket, connected to a tube frame, that holds the organ vessel. (*See* Bacchi at column 8, lines 1-7 and Figure 2). As such, Bacchi discloses a connection device of a tube frame, rather than of a portable housing. None of the other applied references disclose this claimed feature.

Thus, for at least these reasons, claim 13 is patentable over the applied references.

Accordingly, Applicants respectfully request that the rejection of claim 13 be withdrawn.

IV. New Claims

By this Amendment, new claims 48 and 49 are presented. New claims 48 and 49 depend from claims 47 and 1, respectively, and, thus, distinguish over the applied references for at least the reasons discussed above with respect to claims 1 and 47.

Additionally, as the Examiner agreed during the personal interview, none of the applied references disclose or would have rendered obvious tubes held in predetermined positions, wherein each predetermined position is configured to be horizontally aligned with the location of the one or more openings (claim 49). Furthermore, none of the applied references disclose or reasonably suggest tubes that are horizontally aligned within the tube frame on the same plane (claim 48). Thus, prompt examination and allowance of new claims 48 and 49 are respectfully requested.

V. Rejoinder

Applicants respectfully request rejoinder of claims 27-46. It is respectfully submitted that the subject matter of all claims is sufficiently related that a thorough search for the subject matter of any one Group of claims would encompass a search for the subject matter of the remaining claims. Thus, it is respectfully submitted that the search and examination of the entire application could be made without serious burden. See MPEP §803, in which it is stated that "if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions" (emphasis added). It is respectfully submitted that this policy should apply in the present application in order to avoid unnecessary delay and expense to Applicants and duplicative examination by the Patent Office.

In addition, independent claim 27 recites features similar to those recited in independent claim 1. Thus, upon allowance of claim 1, rejoinder and allowance of claim 27, and all of the claims depending therefrom, are respectfully requested.

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Thus, withdrawal of the Restriction Requirement is respectfully requested.

VI. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,

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Rodney H Rothwell, Jr. Registration No. 60,728

WPB:LLT/amw

Attachments:

Petition for Extension of Time Claim Fee Transmittal

Date: August 10, 2009

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